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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 863.804	05/24/2001	Malcolm Wilson Moon	038602-1153	8901

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Beth A. Burrous
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5109

EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/05/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/863,804

Applicant(s)

MOON ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-20, 22 and 24-36 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 9, 14, 16-19 and 24-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 10-13, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-14, 16-20, 22 and 24-36 are currently pending in the current application. Claims 4-5, 9, 14, 16-19, and 24-36 drawn to a nonelected invention are withdrawn from further consideration. Claims 15, 21 and 23 have been cancelled in Paper No. 9. Claims 1-3, 6-8, 10-13, 20 and 22 are rejected.

The amendment filed 21 August 2002 has been considered and entered as Paper No. 9.

Election/Restrictions

The subject matter of claims 1-3, 6-8, 10-13, 20 and 22 other than that wherein:
The compound of formula I as found in claim 1 with the following structure wherein:

R³, R⁴, R⁵, R⁶, R⁷, R⁸, R⁹, R¹⁰, and R^{1'} are as found in claim 1.

R^{3'} and **R^{4'}** form un-substituted pyrrolidin-1-yl.

stands withdrawn under 37 CFR 1.142(b) as being for non elected subject matter, for reasons essentially those given in the last Office action. Applicants' traversal of the restriction requirement has been considered but is not found persuasive. Applicants argue that the examiner has not examined the elected claims as required by MPEP 803.02 and has improperly refused to examine that which the applicants regard as their invention by withdrawing subject matter from claims 1-14, 16-20 and 22.

Firstly, it is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one

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independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. So, here we have claims, which involve more than one independent or distinct invention. Under 35 U.S.C. 121, the claims may be restricted and the examination limited to a restricted invention. There is no argument or evidence to the contrary. Accordingly, restriction as has been presented in this application is proper. The requirement to restrict is repeated and made final.

Objections

Claims 1-3, 6-8, 10-13, 20 and 22 are objected to as containing non-elected subject matter.

Specification

The objections to the specification have been overcome in the Amendment filed 21 August 2002 by the amendments to the specification

Double Patenting

Statutory type (35 U.S.C. 101) double patenting

This provisional statutory double patenting rejection has been overcome by applicants arguments in Paper No. 9, the amendment filed on 21 August 2002.

Non-statutory double patenting

The provisional Non-statutory double patenting rejection with Application No. 09/863905 is maintained and is now a Non-statutory double patenting rejection with US

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Patent No. 6,451,838. It is noted that on page 5 of applicant's response filed 21 August 2002 applicants submit that upon completion of examination, applicants will file a duly executed Terminal Disclaimer to the non-statutory double patenting rejection as found in Paper No. 8. Claims 6 and 8 are also now rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 4 of US Patent No. 6,451,838. Essentially for the same reasons as found in Paper No. 8 and repeated below.

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-3, 7, 10-13, 20, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6, and 8 of US Patent No. 6,451,838. Specifically, claims 1-3 and 10-13 are rejected over claim 1 of the US Patent, instant claim 7 is rejected over the US Patents claim 3, instant claim 20 is rejected over the US Patent claim 6, and instant claim 22 is rejected over the US Patent claim 8. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants claims 1-3, 7, 10-13, 20 and 22 teach the compound of formula (I) wherein $R^{1'}$ can be hydrogen or alkyl (claims 1-3 and 6) and pharmaceutical compositions of the compound of formula (I) (claim 20) which can be administered parentally (claim 22). Applicant further limits the compound of formula (I) to compounds where R^3 , R^4 , R^5 , R^6 , R^7 , and R^9 are hydrogen and R^8 and R^{10} are un-substituted lower alkyl such as methyl (claims 6, 7, 8 and 10) and where R^9 is C-amido or lower alkyl substituted with carboxy (claims 11-13).

Claims 1-4, 6 and 8 in US Patent No. 6,451,838 disclose the compound of (I) which has hydrogen in the same position as that of $R^{1'}$ in the instantly claimed compound of formula (I) (claim 1) and pharmaceutical compositions of the compound of formula (I) (claim 6) which can be administered parentally (claim 8). US Patent No. 6,451,838 further limits the compound of formula (I) to compounds where R^3 , R^4 , R^5 , R^6 , R^7 , and R^9 are hydrogen (claims 2 and 3) and R^8 and R^{10} are un-substituted lower alkyl (claim 3 and 4).

The difference between the claims at issue and US Patent No. 6,451,838 is that hydrogen must be in the position where $R^{1'}$ is in the instant claims, and $R^{1'}$ in the instant

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claims may be hydrogen or alkyl. In regards to instant claims 11-13, claim 1 of the US Patent encompasses this embodiment, but there is no further limiting claim in the patent for R⁹ to be C-amido or lower alkyl substituted with carboxy.

However, it would have been obvious to someone of ordinary skill in the art, when faced with US Patent No. 6,451,838 to prepare compounds where one of the hydrogens on the methyl of the 1-pyrrolidinylmethyl of the compound of formula (I) would be replaced with methyl (applicant is currently claiming alkyl which encompasses methyl) since it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). In regards to R⁹, it would have been obvious to prepare compounds where R⁹ is C-amido or lower alkyl substituted with carboxy since this is encompassed by claim 1 of the US Patent and is a preferred substituent as is seen on page 2 and 3 [0028] of the US Patent. The motivation to make the instantly claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., inhibition of protein kinase).

Provisional Non-statutory Double Patenting

Claim 1-3, 6-8, 10-13, 20 and 22 of this application conflict with claims 1-4, 6 and 8 of Application No. 10/243663. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

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Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1-3, 7, 10-13, 20, and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6, and 8 of co-pending application 10/243663. Specifically, claims 1-3 and 10-13 are rejected over claim 1 of the co-pending application, instant claim 7 is rejected over the co-pending claim 3, instant claim 20 is rejected over co-pending claim 6, and instant claim 22 is rejected over co-pending claim 8. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants claims 1-3, 7, 10-13, 20 and 22 teach the compound of formula (I) wherein $R^{1'}$ can be hydrogen or alkyl (claims 1-3 and 6) and pharmaceutical compositions of the compound of formula (I) (claim 20) which can be administered parentally (claim 22). Applicant further limits the compound of formula (I) to compounds where R^3 , R^4 , R^5 , R^6 , R_7 , and R^9 are hydrogen and R^8 and R^{10} are un-substituted lower alkyl such as methyl (claims 6, 7, 8 and 10) and where R^9 is C-amido or lower alkyl substituted with carboxy (claims 11-13).

Claims 1-4, 6 and 8 in co-pending US application 10/243663 disclose the compound of (I) which has hydrogen in the same position as that of $R^{1'}$ in the instantly claimed compound of formula (I) (claim 1) and pharmaceutical compositions of the compound of formula (I) (claim 6) which can be administered parentally (claim 8). The co-pending US application further limits the compound of formula (I) to compounds where R^3 , R^4 , R^5 , R^6 , R^7 , and R^9 are hydrogen (claims 2 and 3) and R^8 and R^{10} are un-substituted lower alkyl (claim 3 and 4).

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The difference between the claims at issue and the co-pending Application No. 10/243663 is that hydrogen must be in the position where R^1 is in the instant claims, and R^1 in the instant claims may be hydrogen or alkyl. In regards to instant claims 11-13, claim 1 of the co-pending application encompasses this embodiment, but there is no further limiting claim in co-pending Application No. 10/243663 for R^9 to be C-amido or lower alkyl substituted with carboxy.

However, it would have been obvious to someone of ordinary skill in the art, when faced with co-pending Application No. 10/243663 to prepare compounds where one of the hydrogens on the methyl of the 1-pyrrolidinylmethyl of the compound of formula (I) would be replaced with methyl (applicant is currently claiming alkyl which encompasses methyl) since it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). In regards to R^9 , it would have been obvious to prepare compounds where R^9 is C-amido or lower alkyl substituted with carboxy since this is encompassed by claim 1 of the co-pending application and is a preferred substituent as is seen on page 2 and 3 [0028] of the co-pending application. The motivation to make the instantly claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., inhibition of protein kinase).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

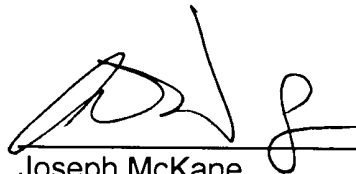
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600



Joseph McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600